

**Amendments to the Drawings:**

The attached 6 sheets of drawings are replacements for those originally filed as per the Examiner's instructions. As instructed by the Examiner, the replacement sheets are prepared by a professional draftsman. Some of the figures are in color and a petition for the inclusion of color drawings is being filed with this response.

No new matter has been added in these replacement sheets.

Attachment: Replacement Sheets 1-6

## **REMARKS/ARGUMENTS**

### Specification:

The Specification has been amended to correct spelling errors of the name of the plant from which the inventive extract is derived. The correct spelling of the plant from which the root extract is derived is *Pueraria tuberosa*.

### The Rejection of Claims 1-8, under 35 USC 112, First Paragraph:

Applicants acknowledge that Claims 1-8 are rejected under 35 U.S.C. 112. The Examiner states that while the specification does provide enablement for an in vitro method of treating and/or reducing the risk of development of type II diabetes, said method comprising a step of administering a pharmaceutically effective amount of a root extract of plant *Pueraria tuberosa* or butanol fraction of the extract or Lupinoside A4 (LPA4), optionally along with additive(s) to cells, it does not reasonably provide enablement for preventing type II diabetes in a subject in need thereof comprising the administration of any and all extracts of the claim-designated plant to a subject in need thereof, and wherein the subject is either an animal or a human being.

Claim 1 has been amended to claim an in vitro method directed to treating and/or reducing the risk of development of type II diabetes comprising the administration of a pharmaceutically effective amount of the invention root extract of the plant *Pueraria tuberosa*, a butanol fraction of the extract or Lupinoside A4 (LPA4), optionally along with additives to cells. Dependent claims 2-8, as now amended, are drawn to a method as claimed in claim 1, wherein said method of preventing and/or reducing the risk of development of type 2 diabetes is by means of augmenting Glut4 phosphorylation and Glut4 translocation to enhance insulin signal in a signal transduction pathway, wherein the extract is an aqueous extract, wherein the extract is obtained from root of the plant, wherein the additive is selected from the group comprising nutrients such as proteins, carbohydrates, sugars, talc, magnesium, stearate, cellulose, calcium carbonate, starch, gelatin paste, pharmaceutically acceptable carrier, excipients, diluent, and solvent, wherein said method shows an increase in glucose uptake by the cells, wherein said method is

nontoxic to said cells, and wherein said extract prevents palmitate induced defects on insulin signaling.

The in vitro method as now claimed is enabled by the specification as originally filed. Page 10, lines 1-13 describe the treatment of cells with a root extract of *Pueraria tuberosa* showing LPA4, the active ingredient in the invention extract to be highly effective in attenuating the effects of FFA-induced impairment of insulin activity; a key indicator of type II diabetes.

Therefore, in light of the claim amendments, Applicants respectfully submit that Claims 1-8 as amended are enabled by the specification and overcome the Examiner's 35 USC 112, first paragraph rejection.

The Rejection of Claims 1-8, under 35 USC 112, Second Paragraph:

Claims 1-8 have been rejected under 35 USC 112, second paragraph for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. The Examiner states that Claim 1 is rendered vague and indefinite by the term "extract" because this term in and of itself, does not adequately delineate its metes and bounds. She states that the step(s) by which the claimed extract is obtained "must be recited in the claim language itself (i.e. as a product-by-process). Claim 1 has been amended to distinctly claim the root extract of the plant *Pueraria tuberosa*, a product-by-process. Applicants respectfully submit that Claim 1, as now amended, overcomes the 35 USC 112, second paragraph rejection.

Applicants acknowledge the Examiner's statement that there is insufficient antecedent basis for the limitation of "the concentration range" in Claims 6 and 7, lines 1-2 but this may be overcome by replacing "the" with "a". Claims 6 and 7 have both been amended and now include proper antecedent language. Applicants respectfully submit that the changes to the claims render these claims in condition for allowance.

The Examiner also states that there is insufficient antecedent basis for the limitation of "the administration route" in line 1 of Claim 8. Claim 8 has also been amended to include proper

antecedent language. Applicants respectfully submit that Claim 8 is now in condition for allowance.

Claim Objections:

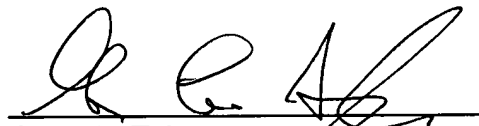
Claim 1, line 3: Examiner has pointed out the misspelling of the plant from which the invention extract is derived. The claim has been amended to correct the misspelling. Applicant submits that this correction overcomes the objection.

CONCLUSION:

A petition for an extension of time and a petition for inclusion of color drawings are being filed with this response with the required fees attached. Other than this, no additional fees are believed due for this response. The Commissioner is hereby authorized to charge any additional fees or credit any overpayment to Deposit Account No. **13-0010 (KSP-1001US)**.

Respectfully submitted,

Dated: September 8, 2006

  
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EXPRESS MAIL CERTIFICATE

"EXPRESS MAIL" LABEL No: EV757058007US

Date of Deposit: Sept. 11, 2006

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above, addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

  
Beth Naul